

ThromboGenics in pact with Bharat Bio to make THR-100

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Hyderabad, Dec. 7: Brussels-based ThromboGenics, a biotechnology company focused on vascular disease, has completed a license agreement with Bharat Biotech International Ltd for manufacturing, clinical development and commercialisation of THR-100, a novel variant of Recombinant Staphylokinase, in developing as well as certain industrialised countries. THR-100 is a thrombolytic agent developed for treatment of acute myocardial infarction (AMI or heart attack) and other vascular diseases based on its ability to dissolve blood clots.

In return for granting this licence, ThromboGenics will earn royalties on net sales and Bharat Biotech will assume responsibility for all future costs, according to company officials. THR-100 has completed phase II clinical trials in Europe for treatment of AMI in over 140 patients. In the clinic, THR-100 has demonstrated efficacy equivalent to tPA, or tissue plasminogen activator (considered as the 'gold standard' for thrombolytic therapy), but at significantly lower patient cost than tPA. THR-100 has also shown superior efficacy to both streptokinase and urokinase, the most commonly used thrombolytic agents in the developing world for the treatment of AMI and other thrombotic conditions.

According to Krishna Ella, CMD, the agreement is to develop and commercialise THR-100 as a replacement for established thrombolytics, such as streptokinase and urokinase, in developing markets.

As part of this licence deal, ThromboGenics will transfer its THR-100 technology to Bharat Biotech, which will become the global manufacturer for the finished drug. With input from ThromboGenics, Bharat Biotech will be responsible for developing the commercial manufacturing process, implement a clinical development plan for phase III trials, and gain marketing authorisation to commercialise THR-100, initially in India. Entry into markets outside of India is also planned as part of this alliance.

"ThromboGenics has been on the cutting edge of research and development of new products for vascular diseases. This partnership will help us bring a thrombolytic molecule to the developing world that is comparable in efficacy to tPA at affordable costs," Ella said.